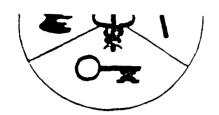
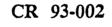
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DIRECTORATE OF HEALTH CARE STUDIES AND CLINICAL INVESTIGATION

ASSESSMENT OF TWO DATA COLLECTION APPROACHES FOR FORT BRAGG CHILD/ADOLESCENT MENTAL HEALTH DEMONSTRATION PROJECT USING POWER ANALYSIS



PART I-FINAL REPORT (REVISED)

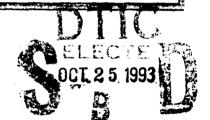


UNITED STATES ARMY

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ASSESSMENT OF TWO DATA COLLECTION APPROACHES FOR FORT BRAGG CHILD/ADOLESCENT MENTAL HEALTH DEMONSTRATION PROJECT USING POWER ANALYSIS

A REPORT TO
THE ASSISTANT SECRETARY OF DEFENSE
(HEALTH AFFAIRS)

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Clinical Investigation

CR 93-002
Part I - Final Report (Revised)
June 1993

UNITED STATES ARMY
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BACKGROUND

In response to inquiries from Congressional representatives, the Acting Assistant Secretary of Defense (Health Affairs) requested that the Army document a Department of Defense (DoD) position regarding an extension of the Fort Bragg Mental Health Demonstration Project. It was requested that the Army establish a panel of Army/DoD experts (psychiatrists, psychologists, other clinicians, and clinical statisticians) to review the evaluation and other related data concerning the Demonstration Project in order to: (1) support a DoD position on the level of confidence necessary to confirm treatment results/conclusions, and (2) indicate the impact of an Army approved evaluation due date on that level of confidence.

This technical report presents an independent statistical analysis/review. No actual data from the Fort Bragg Child/Adolescent Mental Health Demonstration Project or the Fort Bragg Evaluation Project were made available. However, information contained in a letter (shown as Appendix A) written by Dr. Lenore Behar, Ph.D., Head of the Child and Family Services Branch, North Carolina Department of Human Resources, to Mr. Leo Sleight, Central Contracting Office, Department of the Army, Headquarters U.S. Army Health Services Command, Fort Sam Houston, Texas, dated February 15, 1993, was provided by Vanderbilt University. In the letter, Dr. Behar presented two data collection plans. These plans, one Short-Term and one Long-Term, differ in the number of cases collected at 'Wave 3'. The effectiveness of each plan was described by means of a power value of a statistical test for detecting differences in improvement in mental health outcomes between Demonstration and Comparison cases. In addition, a reprint of a paper submitted to the 1992 American Psychological Association Convention addressing power analysis in psychotherapy research was furnished. This paper is included as Appendix B. Also submitted was documentation supporting the power values in Appendix A in materials attached to a letter dated April 30, 1993, written by Dr. Leonard Bickman, Ph.D., Director of the Center for Mental Health Policy, Institute for Public Policy Studies, Vanderbilt University, to LTC Thomas E. Leonard, Headquarters U.S. Army Health Services Command, Fort Sam Houston, Texas. Pertinent portions of this documentation are included as Appendix C.

POWER ANALYSIS COMPARISON OF TWO DATA COLLECTION PLANS

Power Analysis Assumptions.

In the statistical assumptions presented in Appendix A, the type of variable(s) used to measure 'improvement' between an average Demonstration case and an average Comparison case was

not defined. The paper shown in Appendix 3 was referenced instead, presenting the results of a meta-analysis for 12 categories of outcome measures, six each for behavioral and nonbehavioral treatments. It appears that the Fort Bragg Evaluation Project used the Appendix B paper to obtain the value of the effect size (ES) for Normed Rating Scales--Nonbehavioral Treatment outcome measures--as this value is included in Appendix A. In Appendix A (p. A-6), it is stated that the Short-Term Plan has 50% power and the Long-Term Plan of data collection would have 80% power. These levels of power were based on a simulation model submitted by Vanderbilt University (Appendix C).

The effect size (ES) index identified as d by Cohen (1988), is the standardized difference between two population means. This equation is as follows:

$$d = \frac{m_A - m_B}{\sigma}$$

where d = ES index for t test of means,

 m_A , m_B = population means,

and σ = standard deviation of either population (equal variance is assumed).

The effect size value (ES = 0.25) derived in Appendix B (p. B-2) and cited in Appendix A (p. A-5) should be used with caution for several reasons. First, this value was computed for a series of 12 sub-group samples. The Normed Rating Scale used to derive the power in Appendix A was based on a mean sample of only 33 cases. The authors of the Appendix 3 paper stated this problem of variability as follows (p. 3-2): "The large discrepancies between sample sizes actually used and those necessary to attain an acceptable level of power in the studies shown in Table 1 make it difficult to assess how closely the obtained treatment effect sizes represent true population effects. This, in turn underscores the need for researchers to attend to power considerations when planning therapy outcome studies." When a meta-analysis is based on such a small size the probability of error is high. As a result, the mean effect size (ES = 0.25) used in Appendix A may or may not express score distances (in units of variability) for the actual variables measuring health outcome in the Fort Bragg Evaluation Project.

Secondly, there is always a risk that meta-analysis may have employed inappropriate assumptions with regard to the validity of pooling and generality. For instance, the meta-analysis may contain some bias as to how the outcome should be produced, excluding some relevant trials from analysis. In other instances, meta-analysis may use multiple results from the same study, and because the results are not independent they may

bias or invalidate the meta-analysis. In other cases, the independent studies may include different measuring techniques and definitions of variables, so the outcomes may not be comparable. In general, effect sizes in unique areas are likely to be small (ES = 0.20 or ES = 0.30), but only a pilot test would give an answer as to the probable magnitude of the ES index for the particular variable of interest in a particular situation.

The power and sample size tables (Cohen, 1988)³ for the above specified ES = 0.25 in Appendix A are designed to analyze the difference between means of two independent samples of the same size drawn from normal populations with equal variances (using the t test for means). If these assumptions cannot be made, which is often the case, the additional adjustments that follow are explicitly supported by Cohen (1988)⁴ and others. Computations should be performed to obtain the harmonic mean if samples of different sizes but equal variance are present, and the root mean square should be computed if two samples of the same size having unequal variances are present. If both sample sizes and variances differ, the values for power formulas from the tables cited in Appendix A may not be valid.

Since no actual data were available from the Fort Bragg Evaluation Project, this review will utilize the data used by Vanderbilt University for this analysis. Appendix A contains a comparison of the two data collection plans using power analysis. The Appendix A power analysis comparison presents the number of cases after attrition for both the Short-Term and Long-Term Plans (p. A-6). For the Short-Term Plan, 299 Demonstration cases and 150 Comparison cases were expected. The following power analysis is based on Cohen's formulas and uses the information supplied in Appendix A. This analysis is followed by a discussion of the simulation submitted by Vanderbilt University and included as Appendix C.

Power Analysis of Short and Long-Term Plans.

Under the assumption that the variances in the Demonstration and Comparison sites are equal, the harmonic mean (n) of the Demonstration sample size (n_D) and the Comparison sample size (n_C) is given by the formula (Cohen, 1988):⁵

$$n = \frac{2n_{D}n_{C}}{n_{D} + n_{C}} = \frac{2(299)(150)}{299 + 150} = \frac{89,700}{449} \approx 200.$$

The value for power of the t test of the Demonstration case mean (m_D) and the Comparison case mean (m_C) testing the null hypothesis that $m_D=m_C$ at $\alpha_1=0.05$ (one-tailed test) (Table 2.3.2 from Cohen, 1988) gives the following results:

for n = 200 and ES = 0.20, power = 0.64, and for n = 200 and ES = 0.30, power = 0.91.

The effect size, proposed in Appendix A and derived from a meta-analysis performed in Appendix B, is 0.25. A linear interpolation was performed to derive the power of the t test for ES = 0.25. This computation yielded a power of 0.78 for ES = 0.25, α_1 = 0.05 and n = 200. This power of 0.78 (78%), as computed for the Short-Term Plan, is much higher than the 0.50 (50%) quoted in Appendix A. A full precision computation of the power for the Short and Long-Term Plans is presented in the next section of this report.

The Long-Term Plan projects 426 Demonstration cases and 361 Comparison cases. This harmonic mean, computed under the assumption that the variances are the same, is as follows (Cohen, 1988):

$$n = \frac{2n_D n_C}{n_D + n_C} = \frac{2(426)(361)}{426 + 361} = \frac{307,572}{787} = 390.8 \approx 391.$$

Employing Table 2.3.2 in Cohen (1988), 8 n = 350 yields power = 84% for ES = 0.20 and power = 99% for ES = 0.30. For n = 400, power = 88% for ES = 0.20 and power is greater than 99% for ES = 0.30. The linear approximation yields a power of 93.3% for ES = 0.25 (for n = 391).

Computational Procedure for the Exact Power of the Short and Long-Term Plans.

The linear interpolation to compute power, discussed on pages 3 and 4, was justified by its simplicity and by the relatively accurate values obtained. The full precision in computing the power for the Short and Long-Term Plans was based on the expression (Cohen, 1988):

$$z_{1-\beta} = \frac{d(n-1)\sqrt{2n}}{2(n-1) + 1.21(Z_{1-\alpha_1} - 1.06)} - z_{1-\alpha_1}$$

where $z_{l-\beta}$ = the percentile of the standard normal distribution giving the power value $z_{l-\alpha_i}$ = the percentile of the standard normal distribution for α_l significance level d = the effect size ES and n = the harmonic mean.

For the Short-Term Plan, the following information was available:

n = 200 $\alpha_1 = 0.05$ d = 0.25 $z_{1-a} = 1.645$.

The $z_{1:\beta}$ percentile was computed under these assumptions from the above formula:

$$z_{1-\beta} = \frac{(0.25)(200 - 1)\sqrt{2(200)}}{2(200 - 1) + 1.21(1.645 - 1.06)} - 1.645$$

$$= \frac{(0.25)(199)(20)}{398 + (1.21)(0.585)} - 1.645 = \frac{995}{398.708} - 1.645$$

$$= 2.496 - 1.645 = 0.851.$$

The probability for this $z_{1.\beta}$ percentile was found from the Normal Curve Areas Table C (Daniel, 1988). This probability presents the power of the test and is equal to 80.258%. The Short-Term Plan gives a statistical power (computed with full precision) exceeding 80%.

A similar computation was performed for the Long-Term Plan under the following assumptions:

n = 391 $\alpha_1 = 0.05$ d = 0.25 $z_{1-\alpha_1} = 1.645$.

The $z_{1-\beta}$ percentile found from the same formula (Cohen, 1988) 11 was computed as follows:

$$z_{1-\beta} = \frac{(0.25)(391 - 1)\sqrt{(2)(391)}}{2(391 - 1) + 1.21(1.645 - 1.06)} - 1.645$$

$$= \frac{(97.5)(27.964)}{780 + 0.70785} - 1.645 = \frac{2,726.516}{780.708} - 1.645$$

$$= 3.492 - 1.645 = 1.847.$$

The power for this value of $z_{1,3}$ found from the Normal Curve Areas Table C (Daniel, 1988) 12 is equal to 96.78%.

Additional Power Computations.

The power analysis shown above projects that the number of cases in the Short-Term Plan is currently sufficient to draw statistically significant conclusions with high statistical power (80.258%). An additional reason for this conclusion is found by using the sample size tables provided by Cohen (1988)¹³ and deriving the sample size necessary to achieve full 80% power. Sample size tables provide data for two homogeneous normally distributed populations from which random samples of the same size were derived. The ES specified in Appendix A is 0.25. This ES level is not tabulated by Cohen (1988).¹⁴ Therefore, to find the sample size for an untabulated effect size, the following formula is used (Cohen, 1988):¹⁵

$$n = \frac{n_{.10}}{100d^2} + 1$$

where $n_{.10}$ is the sample size for desired power, given \propto and ES = 0.10, and d is the effect size.

In addition, if the sample sizes are not equal, one sample size is treated as if fixed, while the other is computed. When the choice is arbitrary, it is generally supported that n_c be fixed and n_b be computed. To find n_b , the following formula is used (Cohen, 1988):¹⁶

$$n_D = \frac{n_c n}{2n_c - n}$$

where $n_{\rm c}$ = fixed sample size (Comparison sites), n = value read from the Table 2.4.1 (Cohen, 1988)¹⁷ or computed from the previous equation, and $n_{\rm p}$ = sample size for the Demonstration site.

With the objective to determine the Demonstration case sample size required to yield a power = 80% with α_1 = 0.05 and ES = 0.25, and fixing the Comparison cases at n = 150 (the current level), the formula for computing n is:

$$n = \frac{n_{.10}}{100d^2} + 1 = \frac{1,237^*}{100(0.25)^2} + 1 = \frac{1,237}{6.25} + 1 \approx 198 + 1 = 199.$$

*Source: Table 2.4.1 (Cohen, 1988).18

Next, this value is put into the formula for np:

$$n_D = \frac{n_c n}{2n_c - n} = \frac{(150)(199)}{2(150) - 199} = \frac{29,850}{300 - 199}$$
$$= \frac{29,850}{101} = 295.54 \approx 296.$$

Consequently, 296 Demonstration site patients are needed to assure an 80% power for the test investigating the difference in mental health outcomes between Demonstration and Comparison patients (299 were projected in Appendix A).

The identical procedure was applied to the Long-Term Plan. Given that the Comparison sites consist of 361 cases, and assuming the same conditions ($\alpha_1 = 0.05$, ES = 0.25, power = 0.80), a sample size of 138 cases for the Demonstration site was obtained:

$$n = \frac{n_{.10}}{100d^2} + 1 = 199$$

$$n_d = \frac{n_c n}{2n_c - n} = \frac{(361)(199)}{2(361) - 199} = \frac{71,839}{722 - 199} = \frac{71,639}{523}$$

$$= 127.36 \approx 138.$$

As proposed, in Appendix A, the Long-Term Plan is projected to produce 426 Demonstration cases. Using Vanderbilt University's information taken from Appendix A, the above analysis computes only 138 cases are statistically necessary to achieve 80% power.

Assessment of the Simulation Method.

Vanderbilt University's use of the Monte Carlo simulation method to perform a power analysis in the present situation is an inappropriate application of this type of simulation. Using simulation to compute the power analysis without any information about the actual data is not an appropriate use of either simulation or power analysis. Concerning simulation, Miller and Starr (1969)¹⁹ state:

"...Simulation is not a substitute for knowledge [emphasis by authors]. This cannot he over-emphasized. Simulation is not a method, which, somehow, compensates for lack of knowledge."

In general, simulation should be treated as a technique of "last resort" (Naylor, 1971), " to be used only when analytical techniques are not available for obtaining solutions to a given model. Power analysis gives the correct probability of getting a significant result of Comparison and Demonstration site means only when the effect size is computed precisely (i.e., based on actual data from actual variables in the experiment under consideration).

The use of simulation requires complete information about the process or object. In order to simulate reasonably, the probability distributions of the variables of interest should be known. If these distributions are not known, it is impossible to simulate the process. This position is strongly emphasized by many authorities in operations research (Naylor; Ignizio and Gupta; Buffa; Smith; Banks and Carson; Gibra; and Miller and Starr). It is critical that estimates of parameters of the simulation model be derived on the basis of observations taken from the actual data. Naylor 1971) states:

"... There is very little to be gained by using an inadequate model to carry out simulation experiments on a computer because we would merely be simulating our own ignorance."

Since the Monte Carlo technique presented in Appendix C does not involve actual data, the results obtained from this method may be entirely misleading and not accurate. The simulation shown in Appendix C is based on assumptions regarding the effect size (ES = 0.25). This value, derived from meta-analysis (Appendix B, p. B-2), may not apply to real differences between the mean values of mental health outcomes for the Demonstration and Comparison sites. Another assumption (Appendix A, p. A-5), regarding the average child improvement by 0.3 SD, due to treatment and time, is only theoretical because it is not based on actual data.

As stated above, Monte Carlo simulation should only be utilized when direct data analysis cannot be performed (Gibra, 1973), which is not the case with the Fort Bragg Evaluation Project. In addition, the real probability distributions of all the random variables under consideration must be given (Gibra, 1973), a fact ignored in Appendix C. The Monte Carlo method gives only approximations to sampling distributions (Snedecor and Cochran, 1980). To this extent, the technique itself is subject to sampling error.

Another observation about the Appendix C discussion was that the Monte Carlo method was performed only for one variable (CBCL); no other variables were used. The analysis might had different results if the other variables were considered. Finally, before any simulation model can be accepted it must be verified and validated to identify model biases and erroneous assumptions, if any. The authors of the modeling as reported in Appendix C included no such validation.

Without the use of actual data, the effect size value (derived from the meta-analysis cited in Appendix B) was used to calculate the power in this report. This effect size was recommended by the staff of the Fort Bragg Evaluation Project. Although not considered actual data, the effect size allowed for no additional bias to be created by the Monte Carlo method. The equations used to compute the power of the test of means in this report are supported by numerous authorities in power analysis (Cohen, 1988). To

CONCLUSION

The power values for the directional tests computed in this study and the values given in the proposal in Appendix A are significantly different. Utilizing information available in Appendix A and a methodology well supported in the statistical literature, this study demonstrates that the Short-Term Plan would yield power exceeding 80% (80.258%) at full precision, instead of 50% as presented in Appendix A. Even using linear interpolation, a power of 78% was derived. This study demonstrates that it is unnecessary to extend the duration of the project based on power requirements; the Short-Term Plan should produce high power to demonstrate significance if the alternative hypothesis is true. The Demonstration sample size $n_{\rm D}$ needed to achieve 80% power for the Short-Term Plan (α = 0.05, $n_{\rm C}$ = 150, ES = 0.25) equals 296 cases.

Secondly, because the standardized effect size is a computed variable, it can be modified. This modification can be achieved by any of several methods currently available to the Fort Bragg Evaluation Project staff without any project extension. Variance can be reduced, thereby allowing a decrease in sample size necessary to detect a particular level of effect size at a specified power by increasing quality control in data collection and preparation for analysis. For example, each outcome should be used in as sensitive a form as can be reliably measured (variable of interest should always be measured on a continuum, not dichotomized). Unnecessary dichotomization causes a loss of power in all analyses. Consequently, a much larger sample is necessary to achieve the same power.

Finally, as stated above, a more accurate estimate of the Fort Bragg Evaluation Project effect size is achieved when actual data is utilized and a full post hoc power analysis is conducted. The advisability of performing post hoc power analysis is strongly supported by Cohen (1988), 7 Rossi (1990), 8 Bailar (1992), 9 and numerous authorities on power analysis in the behavioral/medical sciences.

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